

## PATENT SPECIFICATION

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## (54) INSUFFLATOR

(71) We, MILES LABORATORIES INC., a Corporation organised and existing under the laws of the State of Indiana, United States of America, of 1127 Myrtle Street, Elkhart, Indiana 46514, United States of America, do hereby declare the invention for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to insufflators and more especially to an inhaling device for dispensing medicament in finely divided form for use in enabling a patient to inhale therefrom a dispersion of particulate material released from a capsule.

Various insufflators have been proposed and used from which medicament can be inhaled directly into the lungs of a patient. These prior devices have generally relied upon the motion of the air being inhaled causing dispersion of the medicament into the air being inhaled. It has now been found that more reliable operation of an insufflator can be obtained where the patient can use the action of exhalation to distribute or disperse the medicament powder from a capsule ready to be drawn as a dispersed powder into the lungs of the patient upon inhalation.

According to the present invention there is provided an inhaling device for dispensing medicament in finely divided form, comprising a housing, a rotor rotatably carried by the housing, the rotor comprising or being adapted to carry a capsule of medicament with the capsule being located within a chamber within the housing, a mouthpiece connected to the chamber, a passage connecting the chamber and the exterior of the housing, a non-return valve permitting air flow through said passage into the chamber, a drive portion of the rotor adapted to be driven by flow of air therepast, a second passage for directing air from the mouthpiece to the drive portion of the rotor, and a second non-return valve per-

mitting flow of air from the mouthpiece past said drive portion.

Preferably the drive portion is provided in a second chamber within the housing with the two chambers being separated by the rotor which may conveniently be in the form of a disk. The drive portion of the rotor can then comprise a plurality of vanes adapted to be driven by an exhaled flow of air from the mouthpiece through the second chamber.

While the device may be constructed so as to provide mounting means for a single capsule, preferably so located as to extend radially outwards from the axis of the rotor so that when the outer end thereof is opened or pierced spinning of the rotor will help to distribute medicament centrifugally within the medicament chamber, in an alternative arrangement a plurality of capsules may be mounted spaced circumferentially around the axis of the rotor with these capsules being usable in turn as required by the patient. With this latter arrangement conveniently the plurality of capsules may be mounted as part of a blister pack which can be secured to a face of the rotor.

While it is possible for the capsules to be individually opened or pierced as required by the patient before use by opening of the housing it is preferred that capsule opening means are provided selectively operable for breaking or piercing a capsule carried by the rotor. A convenient form of capsule opening means may comprise a plunger manually movable between a rest position and the capsule opening position, the plunger being spring biased to a rest position. If a portion of the rotor is engageable from the outside of the housing for permitting indexing movement of the rotor within the housing the rotor can readily be indexed to align a full capsule with the capsule opening means permitting the capsules in the insufflator to be prepared for use without any opening of the housing by the patient being required. This is of particular convenience when the patient may require immediate relief as all

that he need do is take out the loaded insufflator, open a capsule using the capsule opening means, apply the mouthpiece to his mouth and quickly exhale before immediately inhaling to breath the dispersed particles of medicament into his lungs.

A particularly convenient form of non-return valve comprises flap valves covering orifices through the housing, it being possible for such flap valves to comprise simple flaps of resilient plastics material which are normally in a position closing the orifice passages through the housing.

The invention will be further described, by way of example, with reference to the accompanying drawings, in which:

FIGURE 1 is a front elevational view of an insufflator embodying the invention for use with a single dose of medicament;

FIGURE 2 is a rear elevational view of the insufflator of Figure 1;

FIGURE 3 is an end elevational view of the insufflator of Figure 1;

FIGURE 4 is a detailed view showing the location of an inhalation non-return valve for use in the insufflator;

FIGURE 5 is a view similar to Figure 4 but showing an exhalation non-return valve; and

FIGURES 6 to 8 are views similar to Figures 1 to 3 but showing a multiple dose form of the insufflator.

Referring to the drawings, and in particular to Figures 1 to 3, there is shown a single dose inhalation device comprising a substantially cylindrical housing 1 of high impact thermosetting plastics material provided with transparent end caps. These end caps are screwed into position so as to be removable and carry bearing portions, not apparent in the drawings, for rotatably supporting a rotor 4 within the housing. The rotor is of disk-like form and comprises on one side the mounting 12 for a capsule 14 of medicament to be dispensed and on the other side a series of vanes 6 which, in a manner to be described below, acts as a drive portion for rotating the rotor. An inhalation passage or orifice 3 is provided through the transparent cap adjacent the one side of the rotor while an exhalation passage or orifice 5 is provided through the transparent cap adjacent the other side of the rotor. A mouthpiece 2 communicates with the interior of the housing and comprises a divided entry providing a passage 11 leading to the chamber within the housing containing the vanes 6 and a passage 11 leading to the medicament chamber within the housing within which the rotor supports the medicament capsule 14.

Manually operable capsule opening means 7 are shown at the top of the housing as comprising a plunger 8 which is biased by

a spring 9 to the rest position where a puncturing pin 10 is clear from contact with a capsule 14 carried by the rotor. The plunger 8 is manually depressable against the action of the spring 9 to cause the pin 10 to move towards the axis of the rotor whereby when a capsule 14 is aligned with the pin 10 such depression of the plunger will cause the pin 10 to break or pierce the end of the capsule 14.

Omitted in Figures 1 and 2 are non-return inhalation and exhalation valves 13 and 15 which cooperate with the orifices 3 and 5, respectively. These are shown in cross section in the detail views of Figures 4 and 5, the inhalation valve 13 being shown at the top of Figure 4 in the position closing the orifice 3 which it adopts at rest and when a patient is exhaling through the mouthpiece 2 while the lower part of Figure 4 shows the position adopted by the inhalation valve 13 when the patient is inhaling, air being sucked into the medicament chamber from the outside of the housing through the orifice 3. Similarly Figure 5 shows the exhalation valve 15 in its closed position which it occupies during rest and when the patient is inhaling and its open position which it occupies when the patient is exhaling.

In both instances the valves are simple non-return flap valves which are made of resilient plastics material biased to their closed position. The valve 13 is mounted in a recess in the wall of the end cap of the housing so that it does not project to a position where it could interfere with rotation of the rotor while the valve 15 is mounted simply on the outside of the transparent end cap of the housing normally resiliently to close the orifice 5.

Figures 6 to 8 show an alternative embodiment of insufflator which is adapted to mount a plurality of capsules of medicament. The structure is generally similar to that of Figures 1 to 3 with a housing 21 provided with a mouthpiece 22 and having in transparent end caps an inhalation orifice 23 and an exhalation orifice 25 to be provided with non-return flap valves similar to those illustrated in Figures 4 and 5. A rotor 24 provided with vanes 26 is mounted for rotation within the housing, the vanes being drivable by flow of air from the mouthpiece 22 through the chamber containing the vanes and out through the exhalation orifice 25. On the other side of the disk-like rotor a plurality of mounting means 32 are provided for capsules 34 of medicament. The mounting means 32 are arranged to hold the capsules extending radially from the axis of the rotor thereby upon rotation of the rotor a dispersion of the medicament from a capsule will be assisted by centrifugal ac-

tion, the outer end of the capsule being the part of the capsule opened.

In this embodiment no capsule opening means corresponding with the opening means 7 of the first embodiment are illustrated although such may be provided if required. Instead the user removes an end cap of the housing to provide access in order manually to open a capsule before use of the insufflator or he can use a piercing instrument to extend from the mouthpiece to penetrate the end of a capsule aligned with the mouthpiece passage 31.

As before a portion of the rotor may be engageable exteriorly of the housing to permit indexing of a capsule for opening.

Instead of having individual mounting means for the various capsules they may be formed as a single blister pack which can be attached to one face of the rotor 24.

In an alternative arrangement the rotor and medicament filled capsules may themselves comprise an entirely replaceable unit which can be provided within the housing for replacement by another full unit once all the individual doses have been used.

During use of the insufflator the patient, having loaded the device with one or more capsules, either opens one of the capsules manually before replacing the end cap on the housing or utilises an opening means 7 to open the capsule after closure of the housing. The patient then puts the mouthpiece to his mouth and exhales strongly when the exhaled air passes through the passage 10 past the vanes 6 or 26 and out through the exhalation orifice 5 or 25 causing the rotor to spin at high speed to disperse medicament from the opened capsule into the medicament chamber within the housing on one side of the rotor. The patient then immediately inhales strongly whereupon the valve 15 closes and the inhalation valve 13 opens to permit air to be inhaled through the medicament chamber carrying with it medicament from the chamber into the lungs of the patient.

#### WHAT WE CLAIM IS:—

1. An inhaling device for dispensing medicament in finely divided form, comprising a housing, a rotor rotatably carried by the housing, the rotor comprising or being adapted to carry a capsule of medicament with the capsule being located within a chamber within the housing, a mouthpiece connected to the chamber, a passage connecting the chamber and the exterior of the housing, a non-return valve permitting air flow through said passage into the chamber, a drive portion of the rotor adapted to be driven by flow of air therepast, a second passage for directing air from the mouthpiece to the drive portion of the rotor, and a second non-return valve per-

mitting flow of air from the mouthpiece past said drive portion.

2. A device according to claim 1, wherein the drive portion is provided in a second chamber within the housing.

3. A device according to claim 2, wherein the two chambers are separated by the rotor.

4. A device according to claim 2 or 3, wherein the second non-return valve is provided in a passage connecting the second chamber with the exterior of the housing.

5. A device according to claim 4, wherein the drive portion of the rotor comprises a plurality of vanes adapted to be driven by the flow of air from the mouthpiece through the second chamber and out of the housing through the second non-return valve.

6. A device according to any preceding claim, wherein the rotor is disk-like in form having the drive portion on one side thereof and provided with means for removably mounting a capsule of medicament on the other side thereof.

7. A device according to claim 6, wherein the capsule mounting means are adapted to mount an elongate capsule in a position extending radially outwards from the axis of the rotor.

8. A device according to claim 6 or 7, wherein the capsule mounting means are adapted to mount a plurality of capsules spaced circumferentially about the axis of the rotor.

9. A device according to any preceding claim, wherein capsule opening means are provided selectively operable for breaking or piercing a capsule carried by the rotor.

10. A device according to claim 9, wherein the capsule opening means comprises a plunger manually movable between a rest position and a capsule opening position.

11. A device according to claim 10, wherein the plunger is spring biased to its rest position.

12. A device according to any preceding claim, wherein the non-return valves comprise flap valves.

13. A device according to any preceding claim, wherein the mouthpiece includes two separate passages respectively communicating with the medicament chamber and the drive portion of the rotor.

14. A device according to any preceding claim, wherein the rotor comprises the capsules of medicament and is formed as a single replaceable unit.

15. A device according to any preceding claim, wherein a portion of the rotor is engageable from outside of the housing for permitting indexing movement of the rotor within the housing.

16. An inhaling device for dispensing medicament in finely divided form, con-

5   structed and arranged to operate substantially as hereinbefore described with reference to and as illustrated in Figures 1 to 5 or Figures 4 to 8 of the accompanying drawings.

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